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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,675	01/29/2004	Tom McHale	S63.2-10813US01	5432
499 7590 04/24/2008 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344				
EXAMINER				
SEIVERTSON, RYAN J				
ART UNIT		PAPER NUMBER		
3731				
MAIL DATE		DELIVERY MODE		
04/24/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/767,675

Applicant(s)

MCHALE ET AL.

Examiner

Ryan Severson

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-8, 14, 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Fulton (6,074,374).** Fulton reference discloses a catheter having a shaft (61), a balloon (64) having proximal and distal waists (65) and cone portions (the portions between the waists and the axial center of the balloon surface), and a catheter tip (see figure 3). The catheter tip comprises first and second recessed regions (the regions to either side of radiopaque marker 69). The recessed regions have a reduced cross-sectional area compared to the rest of the catheter shaft and tip. The distal end of the tip (71) is radiused. The catheter tip also comprises a hub portion (72) underneath the balloon. Claims 18-20 are being treated as product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 9-13 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton (6,074,374) in view of Follmer et al. (5,728,065).**

5. Regarding claims 9-11, Fulton reference does not disclose a radiopaque marker flush with the outer surface of the tip. Attention is drawn to Follmer reference, which teaches a radiopaque marker (124) insert molded flush with the tip (see figure 2) to create a tip that has a low profile and can be imaged because the marker does not project radially outwardly from the tip. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to insert mold flush the marker of Follmer reference with the tip of Fulton reference to create a tip that has a low profile yet can be located and guided using conventional imaging techniques.

6. Regarding claims 12, 13, and 15, Fulton reference does not disclose a first region and second region having differing flexibilities. Attention is drawn to Follmer reference, which teaches a catheter tip may have two regions (122 and 114) with the second region (114) being less flexible than the first region due to the reinforcements therein (see column 7, lines 9 and 10), which creates a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device with losing the flexibility in the tip. Therefore, it would have been obvious to one of ordinary skill in the

art at the time the invention was made to make the tip of Fulton reference of two regions wherein the first region is more flexible than the second region, as taught by Follmer reference, to create a device that has a soft atraumatic tip and a stiffer proximal section that allows for pushability of the device with losing the flexibility in the tip.

7. Further regarding claims 12 and 13, the stiffer section has a spring (114).

8. **Claims 16 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton (6,074,374) in view of Follmer et al. (5,728,065) and Chee et al. (5,906,606).** The combination of Fulton and Follmer references discloses the invention substantially in the same manner as has been described above with respect to claim 15. However, the combination does not disclose the second region comprises stiffeners that are carbon fibers. Attention is drawn to Chee reference, which teaches a catheter tip may be reinforced with carbon fibers (see column 7, lines 32-34) to create a device that has the rigidity desired yet is lightweight. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the carbon fibers of Chee to replace the ribbons of Follmer as the reinforcements in the second region to create a device that has the rigidity desired in the second region but reduces the weight of the device by using the carbon fibers instead of larger ribbons.

9. **Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton (6,074,374) in view of Imran et al. (5,766,203).** Fulton reference does not disclose the catheter is a stent delivery catheter. Attention is drawn to Imran reference, which teaches a balloon catheter can be used to deliver a stent to provide permanent support to a weakened vessel. Therefore, it would have been obvious to one of

ordinary skill in the art at the time the invention was made to use the catheter of Fulton reference as a stent delivery catheter, as taught by Imran reference, to deliver a stent to provide permanent support to a weakened vessel.

10. Regarding claim 22, Imran reference discloses a stent mounted about the balloon (see figure 8C).

11. Regarding claim 23, the stent of Imran is an inflation expandable stent (see column 8, lines 36-41).

12. Regarding claim 24, the Imran stent can be self-expanding (column 8, line 56).

13. **Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton (6,074,374) in view of Hamilton et al. (6,514,228).** Fulton reference does not disclose the catheter tip is shaped like a triangle. Attention is drawn to Hamilton reference, which teaches an inner catheter tip may have a triangular cross section if desired. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to shape the catheter tip of Fulton in a triangular shape, as taught by Hamilton reference, as an obvious alternative to the circular catheter shape.

Response to Arguments

14. Applicant's arguments with respect to claims 1 and 16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

16. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571)272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731